Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

HIV testing in Australia

Guidance

Information on the types HIV tests available and guidance for manufacturers and sponsors on clinical performance requirements and risk mitigation strategies for HIV tests supplied in Australia.

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Tests for HIV are in vitro diagnostic medical devices (IVDs). They must be approved by the TGA and included in the Australian Register of Therapeutic Goods (ARTG) before they can be legally supplied in Australia.

There are different types of HIV tests including, laboratory tests, Point of Care Test (PoCT) and self-tests.

Guidance produced by the TGA explains the expectations of manufacturers and sponsors of HIV tests to meet clinical performance requirements and have risk mitigation strategies in place.

Laboratory test

Laboratory tests include donor and diagnostic screening tests and reference tests intended to be used in a laboratory environment by trained laboratory professionals. Samples that are positive (i.e. reactive) when tested with a screening test then undergo confirmatory or additional supplementary testing in accordance with a validated testing algorithm to confirm the positive status before the result is accepted as a true positive. A laboratory test is the only method used to confirm the diagnosis of HIV.

HIV point-of-care test (PoCT)

A HIV point-of-care test (PoCT) is a rapid presumptive screening test for HIV intended to be performed in a clinical setting (i.e. outside the laboratory environment), near to or at the side of the patient by a health professional or appropriately trained user who can interpret the test and provide appropriate clinical support. Confirmation of a positive result is required using a diagnostic laboratory test. False negative results can occur, particularly if testing is performed soon after possible exposure to the virus (e.g. if test is performed within 3 months of possible exposure to the virus). To be included in the Australian Register of Therapeutic Goods (ARTG), HIV PoCT must meet the conditions of approval.

HIV Self-test (unsupervised, at home)

HIV self-tests can be included in the Australian Register of Therapeutic Goods (ARTG) and legally supplied in Australia, subject to them satisfying the applicable regulatory requirements. There are HIV self-tests approved for supply in Australia.

HIV self-tests are rapid presumptive screening tests for HIV intended to be used in the home or similar environment by a lay person. Confirmation of a positive result is required using a diagnostic laboratory test and can be arranged through a medical practitioner. False negative results can occur, particularly if testing is performed soon after possible exposure to the virus (e.g. if test is performed within 3 months of possible exposure to the virus). Medical advice should be sought if there is a risk that you have been exposed to HIV.

It is recognised that individuals can purchase tests for personal use via the internet from overseas suppliers. However, these tests have not been evaluated by the TGA to determine their safety and performance.

More information

- HIV point-of-care tests: Conditions of approval for supply in Australia
- Clinical performance requirements and risk mitigation strategies for HIV tests

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Topics: In Vitro Diagnostic medical devices (IVDs)